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What 's new in sterilisation since... Louis Pasteur ?

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Treasurer



In sterilisation...?



The mortality rate is over 60 % for surgical patients

The Agnew Clinic by Thomas Eakin (1885)



Louis PASTEUR (1822-1895) Arbois







Louis Pasteur said...

"This water, this sponge, this lint with which you wash or cover a wound, may deposit germs which have the power of multiplying rapidly within the tissues...

If I had the honor of being a surgeon, impressed I am with the dangers to which the patient is exposed from the microbes present over the surface of all objects, particularly in hospitals, not only would I use none but perfectly clean instruments, but I would clean my hands with the greatest care, and subject them to a rapid flaming... I would use only lint, bandages, and sponges previously exposed to a temperature of 130 to 150°C " (1878).

<image>





Nicolas APPERT (1749-1841)

Charles CHAMBERLAND (1851 - 1908)



Charles CHAMBERLAND



Chamberland Autoclave (1884)



First hot air sterilizer, made by Gaston Poupinel, introduced into French hospitals in 1885

Killing microbes principles

- Fundamental evolutions given by :
 - Bigelaw and Ball (1920) : heat inactivation
 - Olson and Stevens (1934) : sterilizing value
 - Pflug (70 's) : practical applications for tinned food

New microbes, new resistances

- sterilization is a process able to eliminate viable micro-organisms
- It has not been affected by :
 - new pathologies (such as AIDS, hepatitis)
 - new germs (Legionella)
 - new resistances (Staphylococci, Koch bacillus...)
- Except by a new pathogenic agent : Non Conventional Transmissible Agents (prions)

The Prion (or Non Conventional Transmisible Agent, NCTA)

 It challenges the laws of nature, concerning its resistance, duplication and transmission







Processes & Procedures for NCTA Inactivation

- Only steam sterilisation, or incineration combined with combustion is able to lower prion infectiosity
- Group IV : maximal efficiency processes : combined chemical & physical procedures :
 - NaOH 1 M + 121°C 30 min (GD**)
 - NaOH 1 M or NaClO 2% 1 h and 121°C 1 h (GD**)
 - NaClO 2% 1 h and 134°C 18 min (PL*)
 - NaOH 1 M or NaClO 2% 1 h and 134°C 1 h (PL*)
 - NaOH 1M 1 h and 134°C 18 min (PL*)
- Group V : destruction
 - Incineration at t > 800°C with combustion or pyrolysis

* PL = porous load ** GD = gravity displacement

New technologies (1)

- Single use devices → plastic materials
 → new low temperature sterilisation processes
- In no case for reprocessing them... (strictly forbidden in France, authorized in Germany)



New technologies (2) Steam sterilisation

- Steam sterilisers comply now with stringent standards : EN 285 (large sterilisers) and pr EN 13060 (small sterilisers)
- Their quality (reliability, performance) has been considerably improved





New technologies (3) ethylene oxide

- Philips and Kaye (1949)
- Very flexible sterilisation process
- Carcinogenicity
- Freon as dilutant for EO forbidden
- No efficacy towards NCTA



- Disappearing more and more from hospitals (except for immuno depressed patients) (45 vessels in France)
- Irreplaceable for several industrial applications

New technologies (4) Low Temperature Steam Formaldehyde (LTSF)

- Developed in UK by Hurrell and Line (73 's). Widely used in Sweden, forbidden in France (due to NCTA resistance)
- Low toxicity for personnel and patients
- Very cheap
- But very unstable ; highest difficulties in penetrating plastic or with lumens instruments



New technologies (5) Hydrogen peroxide diffusion and Plasma (Sterrad®)

- Welcomed in the 90 's for replacement of EO
- Easy to use
- Might be efficient on prions
- Restrictions for the devices to be processed (ratio length/diam., cellulose, humidity...)
- Validation to be performed acc. to EN 14 937
- High cost of the process

→ It may be predicted that, in future, only the gas plasma process will survive as low temp ste. process in hospitals



New technologies (6) Ionising radiations (γ rays, X rays, e. beam)

- Only industrial plants
- Subcontracting with hospitals
- No efficacy on NCTA agents













Is steam sterilisation still the N°1 process ?

- Steam sterilisation at the highest temperature (134°C) is the reference process and will remain so for a long time.
- There is no other process that is more efficient, flexible, easy to monitor and control, non-poisonous and economical.
 Steam sterilisation is a revolutionary process

New materials to be processed

- Textiles to be sterilised
 : replaced by non woven materials
- rubber and glass devices : replaced by single-use devices
- instruments more and more made in materials easily and totally dismantled and tolerating 134-18 min
- New devices to be processed (tele or computer assisted surgery, MIS)

Cleaning is the most important step (1)

- Pre-disinfection by soaking in a detergent and disinfectant solute, on the spot, just after use, is a well established practice in some Latin countries
- Pros :
 - personnel protection
 - no slime
 - no airborne contamination during transportation



Cleaning is the most important step (2)

- In opposition : use of a washer-disinfector (pr EN 15 883)
- Pros :
 - automated and efficient
 - technique
 - simplifies the job
- Cons :



- risk of allowing the biological contaminants to dry
- does not protect personnel

New packaging (1) Not complying with EN or ISO standards

These boxes are no longer used, and it is easy to understand why...



New packaging (2) Complying with EN or ISO standards





Containers with permanent filters



Plastic and paper pouches

Unwoven materials

Efficient cycles

Gravity displacement cycles can 't be used for porous loads

Porous load cycle

New controls (1)

- The basis for monitoring cycles is still the trilogy :
 - Bowie-Dick test
 - temperature, pressure
 and time recorder
 - class 6 chemical indicators









New controls (2)

 Electronic devices are not taking place of all the classical methods of control, based on observation and not on measurements







Electronic Bowie-Dick

Data loggers

New controls (3) Validation

- The validation of the processes is fundamental to making sure that the sterilising agent has been able to kill micro-organisms in every area of the load
 - Steam sterilisation : EN 554 (1994)
 - EO or IR sterilisation : EN 550 (1994)
 - Other processes : EN 14 937 (2001)

Quality assurance implementation (1)

- Developed recently in some European countries, but not yet taken up by all
- Points to be fulfilled :
 - definition of responsibilities : who is the real boss ?
 - organization (central services)
 - training : core and specialised; university diploma in France

Quality assurance implementation (2)

- Writing, observing procedures, and recording : basis of any quality system
- Validation of the processes : to be sure to reach the SAL 10⁶
- Using devices which meets the standards

Today, hospital sterilisation is able to reach the desired quality level, as well as in industry.

Let 's insist $\dots(1)$

• Only Central Services are able to address the exigencies of quality.

 Great efforts have to be made in order to remove sterilisation in operating theatres

Let 's insist... (2)

Training is fundamental too...

1993 : first Inter University diploma organised by the Universities of Lyon/Grenoble

(in the Merieux Foundation -Annecy)







ÉTUDES SUPÉRIEURES DE STERILISATION HOSPITALIÈRE 08-19 MARS 2004

Formation ogginisie area le concaus de l'Organisation Mondiale de la Santé, es suns l'églie de l'Association Française de Stérilisation, e de l'International Federation for Sterile Supply, condustat à l'obtention d'au Diplôme Inter-Universitaire de l'Université Caude-Bernard Lyon 1 et de l'Université Caude-Bernard Lyon 1 Formation agéle parle l'hat Cauté de la formation gente l'hat Cauté

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Outsourcing

- Between hospitals
- or with an industrial company specialised in sterilisation (steam, EO or IR)
- is more and more frequent
 - because sterilisation in a quality system is an expensive activity

New regulations in France (1)

- From the 70 's : national standards
- replaced later (90 's) by European or ISO standards
- Concerning all aspects : performance of sterilisers, validation, controls, packaging, def. of sterile state....

New regulations in France (2)

 Several texts have been published to regulate sterilisation activities

• Let 's consider the particular example of France :

New regulations in France (3)

- In any place where sterilisation is performed, at hospital, the preparation of sterile medical devices is under the responsibility of the hospital Pharmacy
- Sterilisation =
 - pre-disinfection
 - +
 - cleaning, checking, packing,
 - sterilisation, monitoring,
 - distribution and storage

on the spot

Under the responsibility of the Pharmacy

New regulations in France (4)

The strength of such a system is that the head of sterilisation has the same power as the surgeon, since both of them are hospital practitioners New regulations in France (5) Who is authorized to work in a CSSD ?

- Pharmacist
- Help-pharmacists (« préparateurs »)
- Nurses
- Help-nurses (« aides-soignants »)
- Technicians : computer, servicing
- Possibly an expert in quality

--> trained to sterilisation practices

New regulations in France (6)

- The sterilisation of medical devices must be performed in a quality system, defined by the Good Sterilisation Practices
 - organization
 - premises (surfaces, airborne contaminations...)
 - personnel
 - techniques

New regulations in France (7)

The validation of every processes has to be performed according to
NF EN 554
NF EN 550
NF EN ISO 14 937

→ Big market !

New regulations in France (8)

 The activity « sterilisation » is subjugated to authorization, after application and inspection of the premises and organization by health authorities (Pharmacy and Conseil de I 'Ordre des Pharmaciens inspection)

New regulations in France (9)

- A person responsible for quality assurance in sterilisation must be appointed in every institution
- A documentary evidence of the implemented quality assurance must be submitted to authorities

New regulations in France (10)

- All these measures are mandatory
- The hospital managers had to consider them
 - → organization in CSSD
 - → implementing a quality system
- \rightarrow plants to be closed
- \rightarrow groupings
- \gg sub-contracting with private companies

New regulations in France (10) Authorizations for sterilisation : the results in 2003

- 2908 health care facilities have a pharmacy
- 1384 have subjugated the authorization for sterilization
- 145 are not authorized (10,5 %)

mainly for reason of their premises (quality of air)

International, European and national associations

 MSÜD - MERKEZÝ STERÝLÝZASYON ÜNÝTELERÝ DERNEÐÝ

http://www.msudtr. org



- Association Française de stérilisation
 http://www.afs.asso.fr
- European Forum for Hospital Sterile Supply EFHSS

http://www.efhss.com

 International Federation for Sterile Supply IFSS GillianSills@aol.com





Conclusion (1)

- Sterilisation is an integral part of infection control
- It has obtained « patents of nobility » due to a collective attitude that remembered its reason for existence and the necessity to operate according to scientific principles in a quality system
- Empiricism in sterilisation may now be over

Conclusion (2)

- Hospital sterilisation forges ahead
- Other developments are still to be expected
- Progress is more likely to come from the quality materials and from the quality control of the cleaning process rather than the sterilisation process itself

Conclusion (3)

« The sterility of a product is not negotiable, because the security of the patient is not negotiable »

The End That's all folks!!